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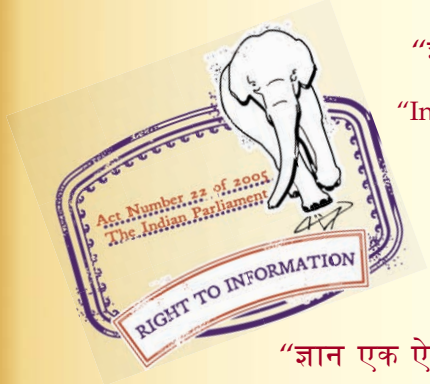
IS 3692 (1975): Rubber Closures, Pharmaceutical [PCD 13: Rubber and Rubber Products]

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Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

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( Reaffirmed 2012 )

# *Indian Standard*

# SPECIFICATION FOR RUBBER CLOSURES, PHARMACEUTICAL

## *( First Revision )*

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INDIAN STANDARDS INSTITUTION
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NEW DELHI 110002

Gr 4

*January* 1976

# *Indian Standard*

# SPECIFICATION FOR RUBBER CLOSURES, PHARMACEUTICAL

# *( First Revision )*

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# *Indian Standard*

# SPECIFICATION FOR RUBBER CLOSURES, PHARMACEUTICAL

# *(First Revision)*

## 0. FOREWORD

**0.1** This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 28 August 1975, after the draft finalized by the Rubber Products Sectional Committee had been approved by the Chemical Division Council.

**0.2** The rubber closures covered in this standard comprise wads (flat rubber discs), plugs (with or without a skirt or flange) and caps (rubber covers held in position on the outside of containers by the tension of the rubber) so as to form with their appropriate seals (*see* IS:2123-1962*) an effective barrier against micro-organisms after sterilization.

**0.3** Rubber closures are available in a number of formulations. For producing suitable closures, various fillers, accelerators and anti-oxidants are mixed with the rubber before vulcanization. As a result, different closures will possess different properties This specification provides for requirements with which the rubber closures shall comply. It has, however, been found impracticable to devise a set of standards which, if complied with, could ensure the compatibility of the rubber closures with pharmaceutical products with which they are used. A test for compatibility shall, therefore, be carried out before a rubber mix is approved. A suggested standardized procedure for such a test has been included in Appendix A. Any proposed change in the composition of an approved rubber mix shall be notified to the user since further compatibility tests may be necessary.

**0.3.1** For the user of rubber closures, concerned with product compatibility for only short periods of time, say three months, and with no facilities for carrying out the test described in Appendix A, a natural rubber with no colouring matter and the minimum of additives (commonly termed as latex rubber) is recommended to produce a suitable closure.

**0.4** In this revision requirement for acetone extract has been deleted and requirements for extractable colour, fragmentation test, self-sealability, *p*H and hardness have been modified.

*Specification for vial (goldie) seals.

**0.5** In the preparation of this standard considerable help has been taken from BS 3263:1960 'Specification for rubber closures for injectable, products' issued by the British Standards Institution.

**0.6** The requirements at Sl No. (vii), (xi) and (xii) of Table 1 call for agreement between the purchaser and the supplier.

**0.7** For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS:2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

## 1. SCOPE

**1.1** This standard prescribes the requirements and the methods of sampling and test for rubber closures suitable for steam sterilization and intended for use with vials of injectable products in the form of aqueous solution or solids to be reconstituted before use. It is not intended for rubber closures to be used for oily injections.

## 2. REQUIREMENTS

**2.1 Material** — The closures shall be made from natural or synthetic rubber or their blends suitably compounded and vulcanized.

### 2.2 Workmanship and Finish

**2.2.1** The closures shall be non-porous, evenly and smoothly finished and free from embedded foreign matter, smears of grease or pigment, and substantially free from blisters, adventitious dust, fibres and loose particles of rubber. In the case of plugs, the top shall be concentric to the plunger.

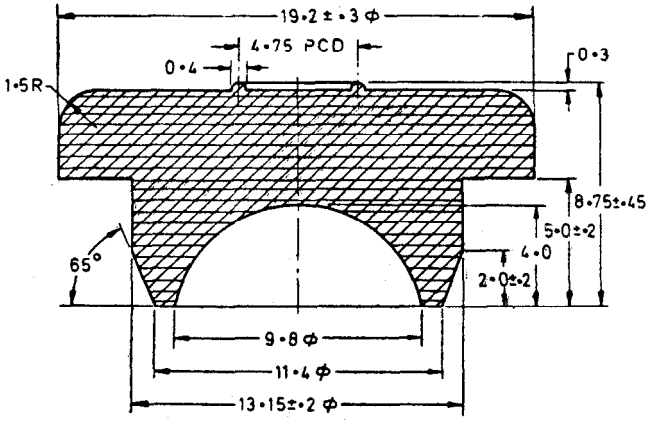
**2.2.2** The closures of each batch shall be of uniform colour.

**2.3** The recommended dimensions of rubber plugs intended for use as closures for glass vials conforming to IS: 1984 (Part I)-1971† are shown in Fig. 1, 2 and 3.

**2.4** The closures shall comply with the requirements prescribed in Table 1.

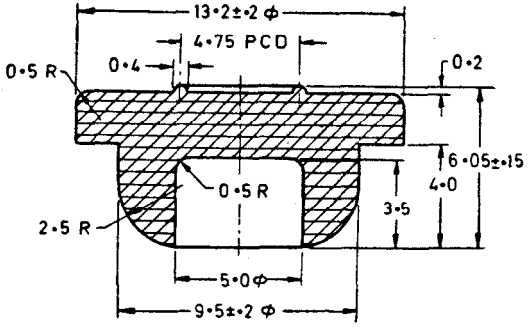
*Rules for rounding off numerical values (*revised*).

†Specification for glass vials for pharmaceutical preparations: Part I Vials for parenteral preparations (*first revision*).



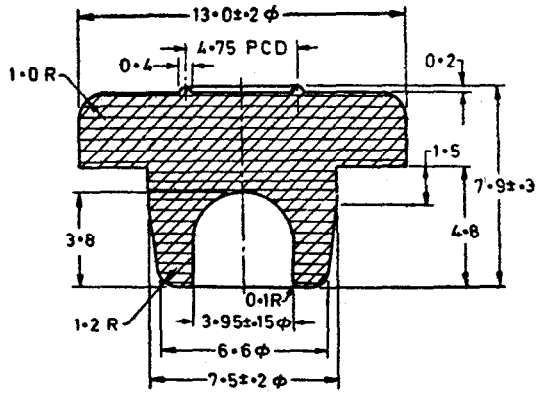

All dimensions in millimetres.

FIG. 1 20 mm RUBBER CLOSURE




All dimensions in millimetres.

FIG. 2 14 mm RUBBER CLOSURE




All dimensions in millimetres.

FIG. 3 13 mm RUBBER CLOSURE

**TABLE 1 REQUIREMENTS FOR RUBBER CLOSURES, PHARMACEUTICAL**

( *Clause* 2.4 )

| SL NO. | CHARACTERISTIC | REQUIREMENT | METHOD OF TEST ( REF TO CL NO. OF APPENDIX B ) |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| i) | Sterilization test | Shall not soften, become tacky and there shall not be any visual change in the closures | B-1 |
| ii) | Extractable matter | No colour or precipitate shall be formed but faint turbidity comparable to the approved sample may be permitted | B-2 |
| iii) | Fragmentation test, for closures made from: | Maximum fragments permitted per 100 punctures: | B-3 |
| | a) Latex ( unfilled ) | 10 | |
| | b) Natural rubber ( filled ) blended with or without synthetic rubber | 40 | |
| | c) Butyl rubber | 60 | |

( *Continued* )

TABLE 1 REQUIREMENTS FOR RUBBER CLOSURES, PHARMACEUTICAL — *Contd*

| Sl No. | Characteristic | Requirement | Method of Test ( Ref to Cl No. of Appendix B ) |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| iv) | Self-sealability | There shall be no spray of water from any of the closures but a small droplet remaining on the surface may be permitted when tested by Method A. The closure shall show no sign of leakage when tested by Method B | B-4 |
| v) | Accelerated ageing | Shall not show any sign of tackiness, softening and other apparent deterioration | B-5 |
| vi) | Free sulphur content, percent by mass, *Max* | 0·2 | B-6 |
| vii) | *p*H of aqueous extract | As agreed between the purchaser and the supplier with a tolerance limit of ± 0·5 on the agreed value | B-7 |
| viii) | Reducing substances in ml, *Max*, for closures made from: | | B-8 |
| | a) Latex ( unfilled ) | 0·5 | |
| | b) Natural rubber ( filled ) blended without or with synthetic rubber | 1·0 | |
| | c) Butyl rubber | 1·5 | |
| ix) | Percent transmission of aqueous extract at 620 nm, *Min*: | | B-9 |
| | a) Latex ( unfilled ) | 95 | |
| | b) Natural rubber ( filled ) blended with or without synthetic rubber | 95 | |
| | c) Butyl rubber | 90 | |
| x) | Heavy metals ( as Pb ) | To pass the test | B-10 |
| xi) | Hardness | As agreed to between the purchaser and the supplier with a tolerance of ± 5 IRHD* | B-11 |
| xii) | Total ash content, percent by mass | As agreed to between the purchaser and the supplier with a tolerance limit of ± 2 percent | B-12 |

*International Rubber Hardness Degrees.

## 3. PACKING AND MARKING

**3.1** The rubber closures shall first be packed in a polyethylene envelope or other suitable substitute and then closed and sealed. These shall then be packed in paper, wooden or other suitable containers.

**3.2 Marking** — The package shall be marked with the name of the manufacturer; recognized trade-mark, if any; and identification in code or otherwise to enable the lot of consignment to be traced back from the records.

**3.2.1** The package may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

## 4. SAMPLING

**4.1 Scale of Sampling and Criteria for Conformity** — For the purpose of ascertaining conformity to this standard, the scale of sampling and criteria for conformity shall be as prescribed in Appendix C.

**4.2** For testing hardness, the manufacturer shall supply a press-cured slab of 75 × 75 × 5·6 mm size having the same rubber compound as the closure and cured under the same conditions as for the latter.

## 5. TEST METHODS

**5.0** All tests shall be carried out within three months of delivery.

**5.1** Tests shall be carried out according to the methods prescribed in Appendix B. Reference to the relevant clause number of the appendix is given under col 4 of Table 1.

# APPENDIX A

(*Clause* 0.3)

## DETERMINATION OF COMPATIBILITY OF RUBBER WITH INJECTABLE PRODUCTS

### A-1. NUMBER OF RUBBER CLOSURES TO BE TESTED

**A-1.1** Wherever possible, take not less than 32, and preferably 50, rubber closures as sterilized by the method prescribed in **B-1**, for each injectable product with which it is intended to test the closures.

## A-2. VIALS

**A-2.1** The vials shall be of the type(s) normally used for the preparations under test. They shall be washed and sterilized by the procedures normal for the preparation.

## A-3. CONTROLS

**A-3.1** Use as many controls as tests prepared from the same batch of vials and the same batch of injectable product, both treated in exactly the same manner as the test sample and sealed with the washed and autoclaved closures normally used and previously found to be acceptable. After sealing treat them in exactly the same manner as the test samples. In the absence of an acceptable closure, use controls of the same batch of injectable product filled into sealed neutral glass ampoules of the same total capacity as the vials to be used in the test and processed in exactly the same manner.

## A-4. PROCEDURE

**A-4.1** Fill the sterile preparations to be used in the test under sterile conditions and using any special necessary filling technique, into the appropriate number of prepared vials, close the vials with the rubber closures under examination and seal them in position in the normal manner.

**A-4.2** Examine the controls of each test and if they are abnormal in any way (for example, colour and clarity) discard the whole test and repeat it. When the controls are satisfactory, examine the appearance of the test samples and, if both the test and control samples are satisfactory, the test may be commenced.

**A-4.3** Place at least the following number of controls and samples of each pharmaceutical preparation under the following storage conditions, half of them in the inverted position:

| *Storage Condition* | *Number of Controls and Sample* |
|---|---|
| 4°C | 4 |
| 25°C | 8 |
| 37°C | 8 |
| 37°C for 16 hours and 4°C for 8 hours alternately, at 85 to 100 percent relative humidity | 8 |
| 50°C or other suitably elevated temperature | 4 |

NOTE — Temperature of 4°C corresponds to the conditions prevailing inside the refrigerator. Tolerances of ± 3°C is permitted for recommended temperatures under storage conditions.

**A-4.3.1** If large numbers of samples are available, store them at the above temperatures in approximately the same proportions as in **A-4.3.**

**A-4.4** Then visually inspect the test and control samples in accordance with the following schedule and record the results:

| *Temperature* | *Interval Between the Start of the Test and Inspection* |
|---|---|
| 4°C | 1, 3, 6, 9, 12 months |
| 25°C | 1, 3, 6, 9, 12 months |
| 37°C | 1, 3, 6, 9, 12 months |
| 37°C for 16 hours and 4°C for 8 hours alternately, at 90 to 100 percent relative humidity | 1, 3, 6, 9, 12 months |
| 50°C or other suitable elevated temperature | 1, 2, 3 months |

**A-4.4.1** It is important that the inspection shall be carried out under standardized conditions of illumination. The sample shall be illuminated by north-light, or a shaded 100-watt electric lamp, the vials being placed directly below the light source at eye level in such a manner that the inspector does not look directly through the container into the light source. A dark background is preferable in most cases. The vials should be swirled by a gentle rotating action and a note made of any foreign insoluble matter. They shall then be inverted gently (to minimize occlusion of air) and reinspected.

## A-5. DISCUSSION AND INTERPRETATION

**A-5.1** It will be found almost invariably that the number of vials showing development of haze or colour varies with the storage temperature, the higher the temperature the greater the number. Primary reliance shall be placed on the samples stored at 25°C and 37°C. Storage at 50°C or above is of importance only in that it may forecast incompatibilities that may show up later at 25°C and 37°C and may, therefore, act as an accelerated test. Storage at 4°C is not important as far as compatibility is concerned, but it serves as a useful check on the initial appearance since little, if any, action will occur at this temperature. Some pharmaceutical preparations, however, are adversely affected by refrigerator storage and many solutions are unstable above 37°C; in these circumstances there is no need to include these temperatures in the test. If these temperatures have been included, the controls will indicate the invalidity of the test. Storage at high humidity is included primarily because of its possible adverse effect on the penetrability, self-sealability and fragmentation of the test closures.

**A-5.2** It shall be understood that after the test, any solution or product tested shall continue to meet the specification for potency, toxicity, bacteriostatic content, etc, in a degree comparable to that of the controls. With closures that appear to be visually satisfactory, it is desirable to carry out the normal specification tests at the same time intervals as the visual inspections and hence the need for more samples. Particularly, it is important that, in the case of dry solids which need to be reconstituted with a solvent, usually water, this reconstitution shall be carried out at regular intervals and the resultant solutions or suspensions examined.

**A-5.3** After the seals have been broken for specified tests to be carried out, the rubber closures shall be removed and inspected for discoloration, swelling, sponginess and any other sign of deterioration. (If the closures are discoloured after being in contact with a liquid, they should be allowed to dry out overnight and re-examined). Any of the above conditions shall be considered evidence of incompatibility. The closures shall also be tested for all tests prescribed in this standard and shall be satisfactory. If it is found that the controls have deteriorated abnormally, the entire test shall be disregarded and the test repeated.

# APPENDIX B

( *Table* 1 and *Clause* 5.1 )

## TESTS FOR RUBBER CLOSURES, PHARMACEUTICAL

### B-1. STERILIZATION TEST

**B-1.1 Procedure** — Pack sufficient number of 'prepared closures' (*see* Appendix A) in silk or nylon bag or in a stainless steel perforated container and autoclave them at a temperature of 120 to 125°C for 30 minutes. Cool the contents and dry the closures in a hot air-oven at 100 to 102°C for 2 hours, except in case of latex rubber (unfilled) closures for which the drying time is reduced to 1 hour. Cool and examine the closures.

### B-2. TEST FOR EXTRACTABLE MATTER

**B-2.1 Procedure** — Place an appropriate number of 'prepared closures' to weigh about 20 g in a conical flask. Add 200 ml of distilled water to the flask and cover the flask with a beaker or with aluminium foil which has been previously washed with acetone. Also add 200 ml of distilled water to another conical flask and cover the flask with a beaker or with aluminium foil as in the case of first flask. This flask serves as a 'control blank'. Autoclave both the flasks for 30 minutes at 120 to 125°C. At the end of 30 minutes, remove the flasks and allow to stand at room temperature for 3 to 5 hours. Examine the colour of the extracted solution. Preserve the extracts for test in **B-8.2**, **B-9** and **B-10**.

## B-3. FRAGMENTATION TEST

**B-3.1 Apparatus** — Hypodermic syringe with needle.

**B-3.2 Procedure** — Half fill 20 vials with water free from extraneous matter and seal in the appropriate manner. Using a 0·8 mm regular point hypodermic needle, pierce each closure five times, normal to the surface, flushing the needle after ever puncture into the vial, ensuring that all the five piercings are made within a circle of 5 mm in diameter and as equidistant from each other as possible. Then remove the needle and examine it carefully for any sign of blunting. If blunting is evident, discard the vial and its contents and substitute by a fresh one. Repeat the above test on the remaining 19 vials. Filter the contents from each vial together with suitable washings through a filter funnel using filter paper of a contrasting colour. (If a white closure is being tested, the filter paper shall be dyed to a contrasting colour, for example, with methylene blue).

**B-3.3** Count the number of rubber fragments on the filter paper, without any artificial aid, for example, magnifying lens.

## B-4. TEST FOR SELF-SEALABILITY

**B-4.1 Apparatus** — Hypodermic syringe with needle.

**B-4.2 Reagent** — Methylene blue solution, 0·1 percent ($m/v$).

**B-4.3 Test Samples** — Use rubber closures sterilized by the method prescribed in **B-1.**

**B-4.4 Procedure for Method A** — Half-fill with water five vials for which the closures are intended, apply the prepared closures and seal in the appropriate manner. Take each vial in turn, invert and inject through the closure a volume of air equal to the volume of air in the vial by means of a 0·8 mm regular point needle (38 mm long) fitted to a hypodermic syringe. Withdraw the needle rapidly and note whether any leakage occurs.

**B-4.5 Procedure for Method B** — Half fill five vials with methylene blue solution prior to closure. Make 5 successive punctures using a 0·8 mm regular point hypodermic needle (38 mm long) in each closure as evenly as possible within a circle 5 mm in diameter. Invert each vial immediately in a separate bottle containing sufficient water to immerse the seal. Apply to each bottle a vacuum of 200 mm of mecury for 30 minutes and examine the seal and the water for sign of leakage through the closure.

## B-5. ACCELERATED AGEING TEST

**B-5.1 Apparatus** — Thermostatically controlled air-oven.

**B-5.2 Test Samples** — Use rubber closures sterilized by the method prescribed in **B-1.**

**B-5.3 Procedure** — Suspend or otherwise support the rubber closures to be tested in a thermostatically controlled air-oven maintained at a temperature of 70 ± 1°C for a period of 168 hours so that the rubber closures are free from strain and exposed to air on all sides but not exposed to light. Provide a suitable mechanical arrangement for a continuous slow change of air in the oven during this treatment. Remove the rubber closures from the oven, cool to room temperature and examine visually.

## B-6. DETERMINATION OF FREE SULPHUR CONTENT

### B-6.1 Reagents

**B-6.1.1** *Bromine*

**B-6.1.2** *Barium Chloride Solution* — Dissolve 10 g of barium chloride in 100 ml of water.

**B-6.1.3** *Acetone — See* IS : 170-1966*.

**B-6.1.4** *Hydrochloric Acid* — conforming to IS : 265-1962†.

**B-6.2 Procedure** — Using clean forceps, transfer 10 closures or a sufficient number of closures to weigh about 10 g, whichever is greater, to a round-bottom flask. Add 100 ml of acetone to the flask and allow to stand overnight. Connect the flask to an efficient reflux condenser, boil and reflux for 8 hours. Cool and transfer the acetone extract completely from the flask to a clean tared platinum crucible of suitable size by washing with acetone. Evaporate carefully to dryness on a steam-bath and dry at 100°C to constant mass. Add to the dried acetone extract, 50 ml of water and 1 to 3 ml of bromine and cover with a watch-glass. Allow the vessel to stand in a water-bath at about 70°C for at least 30 minutes, remove the watch-glass and heat continuously without boiling till the solution is almost colourless. Add 1 ml of hydrochloric acid, filter the solution and dilute it to 250 ml with water. Heat the solution to boiling, and slowly a slight excess of hot barium chloride solution, continue to boil the liquid for 5 to 10 minutes and allow it to stand for one hour at 90 to 100°C.

Filter the liquid through a sintered glass or silica crucible which has been previously washed, dried at 100°C and weighed. After the filtration has been completed, wash the crucible and the precipitate with hot water till the washings are free from chloride, dry at 100°C for one hour, cool in a desiccator and weigh.

*Specification for acetone (*first revision*).
†Specification for hydrochloric acid (*revised*).

**B-6.2.1** Make a blank determination with the reagent, using the same quantities and under the same conditions of test, and apply the correction, if any, to the mass as obtained in **B-6.2.**

**B-6.3 Calculation**

$$\text{Free sulphur content, percent by mass} = \frac{13{\cdot}73\ B}{M}$$

where

$B$ = corrected mass in g of the barium sulphate precipitate, and

$M$ = mass in g of the closures taken for test.

## B-7. DETERMINATION OF *p*H OF AQUEOUS EXTRACT

**B-7.1 Procedure** — From each lot, cut 10 caps into 2 mm pieces. Autoclave the pieces for 5 minutes at a pressure of 40 to 50 kN/m² (approximately 0·4 to 0·5 kgf/cm²) with 200 ml of water. Discard the first extract and repeat the process with another 500 ml of water for 40 minutes. Decant the extract, cool and determine the *p*H with a standard *p*H meter.

## B-8. TEST FOR REDUCING SUBSTANCES

### B-8.1 Reagents

**B-8.1.1** *Iodine Solution* — 0·1 N.

**B-8.1.2** *Starch Solution* — 1 percent ( *m*/*v* ).

**B-8.2 Procedure** — Pipette 50 ml aliquots of the extracted solution of the sample of closures obtained in **B-2** and the control blank solution into two 250 ml conical flasks, add 2 ml of starch solution and titrate with 0·01 N iodine solution to the first permanent blue colour as the end point. The difference between the two titration values is the measure of the reducing substances in the sample solution.

## B-9. TRANSMISSION TEST

**B-9.1 Procedure** — Using a suitable spectrophotometer and using 1-cm cell, read percent transmission of the aqueous extract obtained in **B-2** at 620 nm, using control blank solution as a reference.

## B-10. TEST FOR HEAVY METALS

### B-10.1 Reagents

**B-10.1.1** *Standard Lead Solution* — 1 ml containing 0·01 mg of lead.

**B-10.1.2** *Acetic Acid* — 33 percent.

**B-10.1.3** *Hydrogen Sulphide Solution* — freshly prepared.

**B-10.2 Procedure** — Pipette 10 ml of the aqueous extract (preserved in **B-2**) into a Nessler cylinder; add 10 ml of boiled and cooled distilled water and 1 ml of dilute solution of lead into another Nessler cylinder. Add 2 ml of acetic acid to each of the cylinders. Add 10 ml of solution of hydrogen sulphide (freshly prepared) to each tube. Dilute to 50 ml mark, mix and allow to stand for ten minutes. Compare the colours obtained by viewing the light reflected from the white tile through the cylinder. Colour of the aqueous extract thus treated should not be darker than the standard.

## B-11. DETERMINATION OF HARDNESS

**B-11.1 Procedure** — Perform this test on a press-cured rubber slab of the same compound as used for the closures and cured under the same conditions as for the latter. The minimum dimensions of the slab shall be 75 × 75 × 6·5 mm. Determine the degree of hardness in accordance with the method prescribed in IS : 3400 (Part II)-1965*.

## B-12. DETERMINATION OF THE TOTAL ASH

**B-12.1** Cut the sample rubber closures into small pieces and weigh accurately about 1 g of the sample pieces in a silica crucible. Ignite the test sample at 650 ± 25°C till ashing is complete and constant mass is obtained.

# APPENDIX C

(*Clause* 4.1)

## SAMPLING OF RUBBER CLOSURES, PHARMACEUTICAL

## C-1. SCALE OF SAMPLING

**C-1.1 Lot** — All the rubber closures of the same size and manufactured from the same raw material, under similar conditions of manufacture and in one consignment, shall constitute a lot.

**C-1.1.1** Samples shall be tested from each lot separately for ascertaining conformity of the lot to the requirements of this specification.

**C-1.2** The number of closures to be selected in the sample from a lot shall depend upon the size of the lot and shall be in accordance with Table 2.

*Methods of test for vulcanized rubbers: Part II Hardness.

TABLE 2 SAMPLING OF CLOSURES AND PERMISSIBLE NUMBER OF DEFECTIVES

( *Clause* C-1.2 )

| No. of Closures in the Lot | No. of Closures to be Selected in the Sample | Permissible No. of Defective Closures for Dimension, Workmanship and Finish | No. of Tests to be Performed for Other Characteristics |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| Up to 3 000 | 90 | 2 | 1 |
| 3 001 to 10 000 | 180 | 4 | 2 |
| 10 001 ,, 35 000 | 270 | 6 | 3 |
| 35 001 and above | 450 | 8 | 5 |

**C-1.2.1** Although it is not possible to lay down any fixed rules as to how the samples are to be selected from the packages, it is desirable that the closures should be drawn evenly from as many packages as possible. However, it is recommended that at least 10 percent of the packages should be selected and an equal number of closures drawn at random from each package selected to give the required number of closures in accordance with col 2 of Table 2.

## C-2. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

**C-2.1 Workmanship and Finish** — All the closures selected in the sample ( *see* **C-1.2.1** ) shall be inspected for dimension, workmanship and finish in accordance with **2.2** and **2.3**. A closure shall be considered as defective if it fails to satisfy the requirements of workmanship and finish in any one or more respects.

**C-2.1.1** A lot shall be considered having satisfied the requirements of workmanship and finish if the number of defective closures found as in **C-2.1** does not exceed the applicable permissible number of defective closures.

**C-2.2** For determining the conformity of the lot to the requirements given in Table 1, the number of tests to be carried on a lot shall be in accordance with col 4 of Table 2. For carrying out these tests, the rubber closures selected under col 2 of Table 2 and found satisfactory for dimensions, workmanship and finish shall be used. In case additional closures are required for these tests, they shall also be selected at random from the packages already used for drawing the samples.

**C-2.2.1** All the test results for the different characteristics shall satisfy the requirements of the specification individually.

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